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No. 08-937

IN THE

Supreme Court of the United States

AVENTIS PHARMA S.A. AND
AVENTIS PHARMACEUTICALS INC.,
Petitioners,

v.

AMPHASTAR PHARMACEUTICALS, INC., AND
TEVA PHARMACEUTICALS USA, INC.,
Respondents.

On Petition for a Writ of Certiorari to the
United States Court of Appeals
for the Federal Circuit

BRIEF IN OPPOSITION OF RESPONDENT TEVA PHARMACEUTICALS USA, INC.

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OBJECTION TO QUESTION PRESENTED

The question that Petitioner purports to present is not at issue in this case. As discussed below, the district court did not base its finding of intent to deceive on gross negligence. Instead, the district court made careful credibility findings after considering all the facts and circumstances and concluded that there was "clear and convincing evidence that Dr. Uzan intended to deceive the [Patent Office]." App. 90a.

The Federal Circuit, applying the well established law that both materiality and intent must be proven by clear and convincing evidence and that intent to deceive cannot be presumed from high materiality, affirmed. Petitioner did not argue on appeal that the district court improperly applied a sliding scale to allow intent to be based on gross negligence and the Federal Circuit did not endorse such a standard.

RESPONDENT TEVA'S RULE 29.6 STATEMENT

Pursuant to this Court's Rule 29.6, counsel for respondent Teva Pharmaceuticals USA, Inc. certifies that the parent companies of respondent Teva Pharmaceuticals USA, Inc. are Orvet UK, Teva Pharmaceuticals Europe B.V. (Holland) and Teva Pharmaceutical Industries Ltd. (Israel). All corporations that own 10 percent or more of respondent Teva Pharmaceuticals USA, Inc. are: Teva Pharmaceutical Industries, Ltd.

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Respondent Teva Pharmaceuticals USA, Inc. ("Teva") respectfully requests that this Court deny the petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit.

COUNTERSTATEMENT OF THE CASE

Petitioner asks this Court to review an appellate judgment that the district court did not clearly err in finding that the evidence at trial clearly and convincingly established that Petitioner concealed information highly material to patentability with intent to deceive the patent examiner. Petitioner invokes selected bits of evidence in support of its position, but ignores the full factual record considered by the district court and the adverse credibility findings made concerning the testimony of Petitioner's primary witness, Dr. Uzan. As the Federal Circuit recognized, the evidence as a whole provided ample support for the district court's finding of intent.

Since this Court does not ordinarily grant certiorari to consider whether a circuit court properly reviewed a district court's factual findings, Petitioner attempts to reframe this issue as one of law. Specifically, Petitioner says that the district court inferred intent to deceive the Patent Office from what was at worst gross negligence and that by affirming that decision, the Federal Circuit endorsed a standard that allows inequitable conduct to be established without actual proof of deceptive intent. To the contrary, both the district court and the Federal Circuit expressly recognized that actual proof of intent was required, and concluded that the circumstantial evidence presented warranted an inference of intent.

Facts Found by the District Court

The patent claims at issue are directed to a chemical composition comprising low molecular weight heparins ("LMWHs"). Heparin is a naturally-occurring anticoagulant material consisting of long polysaccharide chains. App. 41a. LMWHs are derived from natural heparin in a process that results in smaller chains. *Id.* The claims encompass mixtures of polysaccharide chains with specified size distributions. App. 3a.

Aventis developed enoxaparin, a LMWH that was approved and marketed successfully beginning in 1987 in Europe. App. 41a. Enoxaparin was covered by European Patent No. 40,144 ("EP '144"), but that patent was revoked in 1990 for lack of novelty, and Aventis was forced to abandon its U.S. counterpart application. App. 41a-42a. Aventis nevertheless sought FDA approval for use of enoxaparin in the U.S. and, as a result, faced what the district court found was "substantial pressure" to obtain U.S. patent protection for enoxaparin. App. 42a.

Accordingly, Aventis filed a patent application for what it said was a "new" formulation of enoxaparin. The critical issue in the prosecution of this application was whether the "new" formulation of enoxaparin was in fact patentably different from the formulation covered by the prior art EP '144 patent. App. 43a. The examiner repeatedly rejected claims to the "new" formulation, questioning whether it was different at all from EP '144 and, even if it were not the same, whether it was nonetheless obvious. App. 4a-10a.

One of the ways Aventis attempted to distinguish its "new" LMWH from the prior art EP '144 product was by focusing on "half-life," i.e., the time in which the compound loses half of its therapeutic effect after administration. App. 43a. The problem Aventis faced, however, was that its internal half-life data showed there was, in fact, very little difference between the "old" and "new" LMWHs. Of the four doses of the claimed LMWH for which Aventis had measured half-life (20, 40, 60 and 80 mg), "*[o]nly the 40 mg dose showed a statistically significant difference over* [the half life of the 60 mg dose of the prior art product]." App. 73a-74a. The specification compared the half-life of only the 40 mg dose of the claimed invention to the 60 mg dose of the prior art product, without disclosing that Aventis possessed other data showing no difference. Indeed, Aventis did not even inform the examiner that it was comparing the two compounds at different dosages.

The district court found that the decision to disclose the favorable data while concealing the unfavorable data

> "gives rise to the natural inference that Aventis sought to achieve by hindsight the appearance of a statistically significant difference where none actually existed; that Aventis and Dr. Uzan engaged in a post-hoc analysis of *** data, 'cherry-picked' the one dose permitting a favorable comparison to [the prior art], and developed in retrospect an analytical framework within which the use of this dose could be rationalized." App. 74a.

The misleading comparison was not "confined to three isolated instances," as Aventis asserts. The undisclosed different dose half-life comparison was

presented first in the specification, then used to argue for patentability in response to the patent examiner's rejection of the claims, and further repeated and expanded in two separate declarations filed by Dr. Uzan in a further effort to overcome the examiner's repeated rejections.

In response to the examiner's first rejection, Aventis referred to the half-life data and argued that because "the inventive formulations and those of the [prior art] European patent exhibit different properties, such as half life, it *necessarily follows that the formulations of the invention could not possibly be the same as those of the European patent.*" App. 57a. Aventis could not have made this argument had it disclosed the difference in dosages. The examiner maintained the rejections in the next office action, noting that Aventis had to "'convincingly demonstrate that the claimed product provides some unexpected or unobvious property not demonstrated by the prior art.'" App. 58a.

In response, Aventis submitted the Dr. Uzan's First Declaration in which Dr. Uzan misleadingly characterized the half-life data in the specification as showing that the claimed formulations had a 250% increase in half-life over the product of the European patent. App. 59a. The examiner noted the first Uzan declaration but maintained the rejection, stating that Aventis had "'failed to provide evidence that the alleged difference between the half life of the [European patent] product and that of the instant mixture is statistically significant.'" App. 60a.

In response to this continued rejection, Aventis filed Dr. Uzan's Second Declaration, which finally revealed the mean half-life and standard deviation

for the 40 mg dose of the claimed invention and compared it to the mean half-life and standard deviation of the prior art product, although the dose of the prior art product remained concealed. App. 45a. Because the dose of the prior art product was never revealed, the examiner did not know that different doses were being compared or that a same dose comparison would show no statistically significant difference in mean half-life. *Id.*

As part of its consideration of the facts and circumstances surrounding this misleading half-life comparison, the district court found that Petitioner's explanations for not disclosing that the half-life comparison was made at different doses changed repeatedly over the course of the litigation and that none of the proffered explanations were credible. These excuses included: (i) an assertion by Dr. Uzan that he thought that he had disclosed the different dosages, (ii) an argument that he used different doses because they were the clinically relevant doses of the products being compared, (iii) an assertion that a different dose comparison was reasonable because the half-lives were dose-independent and (iv) a claim that the failure to disclose that different doses were being compared was inadvertent.

The excuse that Dr. Uzan thought he had disclosed in the specification that different doses were used in the half-life comparison was rejected as unreasonable by the Federal Circuit on the first appeal in this case. App. 102a-103a. The second Federal Circuit panel found that the district court did not clearly err in finding that this excuse did not outweigh the cumulative evidence evincing an intent to deceive. App. 29a.

The district court found none of the remaining excuses credible. In particular, it found the claim that Dr. Uzan compared the claimed invention to the prior art at the "clinically relevant doses" to be a rationalization because "there were a variety of preferred therapeutic doses at the time, depending on the indication." App. 77a. The district court, after finding that Petitioner intended the half-life comparison to address both the anticipation and obviousness rejections issued by the patent examiner, found that a different dose comparison could not show that the two compositions were different, relying on testimony from both the inventor of the patent-in-suit and Petitioner's trial expert. App. 58a, 66a-67a. Based on this evidence, the district court found that Dr. Uzan's "clinically relevant dose" excuse was "unreasonable, because [his] experimental design is unconnected to and inconsistent with his true experimental purpose." App. 67a.

The district court also rejected Petitioner's assertion that a different dose comparison was reasonable here because half-lives are dose independent, finding that the data available to Dr. Uzan did not support such a conclusion. App. 68a-69a.

The district court further found it implausible that Dr Uzan, a respected scientist, had inadvertently presented the data in the misleading manner that they appeared in the patent and his two declarations. Specifically the district court found that "[i]t strains credulity to suggest that a scientist of Dr. Uzan's skills and experience could have relied on logic so flawed purely by accident." App. 83a. In fact, the district court concluded that "Dr. Uzan's

explanation suffers from a total absence of indicia of credibility." App. 88a.

The district court concluded that "[n]egligence played no role in Aventis and Dr. Uzan's failure to disclose the [prior art] dose information." App. 89a. The district court further concluded that Petitioner's repeated failure over the course of the prosecution to disclose to the PTO any information concerning the circumstances of the half-life comparison, which had the effect of concealing the "experimental design mistakes that Dr. Uzan's training, skills and experience strongly suggest he could have never accidentally made," was strong circumstantial evidence of intent to deceive. App. 86a, 90a.

The district court accordingly concluded that this case involved "a statistical analysis designed post-hoc and rationalized in hindsight to fit a hoped-for result" and that there was "clear and convincing evidence that Dr. Uzan intended to deceive the PTO." App. 90a.

Legal Basis For Decisions Below

Contrary to Petitioner's assertion (Pet. at 8), neither the Federal Circuit nor the district court presumed fraudulent intent from materiality. The district court went out of its way to "separately [find] that clear and convincing evidence adduced at trial independently reestablishes—and substantially strengthens—those earlier inferences of intent." App. 87a. Furthermore the district court expressly recognized the controlling Federal Circuit law that materiality alone does not justify a presumption of an intent to deceive. App. 49a. The district court plainly understood that even gross negligence was not sufficient to establish intent to deceive (App. 79a)

and made explicit its finding that "[n]egligence played no role in Aventis and Dr. Uzan's failure to disclose the [prior art] dose information." App. 89a. The district court did not base its intent finding merely on the high materiality of the misleading half-life disclosure, but found intent to deceive "based on the totality of the facts and circumstances surrounding Dr. Uzan's repeated omissions." App. 90a.

The Federal Circuit considered the arguments Petitioner advanced to challenge the district court's finding of intent to deceive and found no clear error. Nothing in the Federal Circuit's decision even suggests that intent may be presumed merely from high materiality or because of gross negligence. To the contrary, the Federal Circuit recognized that "'the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive.'" App. 18a. Only in connection with the final step of balancing the equities, after materiality and intent had already been found, did the Federal Circuit refer to higher materiality allowing a lesser showing of intent. *Id.*

No member of the Federal Circuit dissented from the denial of Petitioner's petition for rehearing *en banc*, not even the judge who dissented from the panel decision. App. 93a.

REASONS FOR DENYING THE PETITION

I. The Standards for Proving the Intent To Deceive Element of Inequitable Conduct Established by the Federal Circuit Were Properly Applied in This Case.

Petitioner asserts that the courts below applied too lenient a standard for establishing intent to deceive. Petitioner's attack misrepresents the standards actually applied by the Federal Circuit and mischaracterizes the nature of prior decisions involving inequitable conduct of both this Court and the Federal Circuit.

A. Neither the Federal Circuit Nor the District Court Allowed Gross Negligence To Satisfy the Intent Element of Inequitable Conduct, Although They Properly Based a Finding of Actual Intent on Circumstantial Evidence, As Is Common When Determining Intent in Other Areas.

The standard applied below for proving the defense of inequitable conduct is not, as Petitioner contends, "effectively a gross negligence standard." The Federal Circuit applied the standard for determining intent to deceive set forth in its *en banc* decision in *Kingsdown Medical Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867 (Fed. Cir. 1988), a standard that Petitioner does not challenge. In particular, the Federal Circuit stated that "[t]o satisfy the intent to deceive element of inequitable conduct, 'the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive.'" App. 18a. (quoting *Impax Labs., Inc. v.*

Aventis Pharms. Inc., 468 F.3d 1366, 1374-75 (Fed. Cir. 2006) (quoting *Kingsdown*, 863 F.2d at 876)).

In *Kingsdown* the Federal Circuit explicitly held that gross negligence is insufficient to satisfy the intent element of inequitable conduct:

> "[A] finding that particular conduct amounts to 'gross negligence' does not of itself justify an inference of intent to deceive; the involved conduct, viewed in light of all the evidence, including evidence of good faith, must indicate sufficient culpability to require a finding of intent to deceive." 863 F. 2d at 876.

Although Petitioner concedes in passing that "the intentionality of certain conduct can be inferred from circumstantial evidence" (Pet. at 16 n.3), the thrust of its petition seeks a rule of law that would prevent inferences of deceptive intent from circumstantial evidence. Since it is well-established in decisions from this Court that such inferences are not only proper but often necessary, and since Petitioner offers no plausible reason to reject this law, the petition presents no question warranting certiorari review.

This Court has long acknowledged the sufficiency of and, indeed, the need to rely on circumstantial evidence in proving intent to deceive. For example, this Court has recognized "that the proof of scienter required in fraud cases is often a matter of inference from circumstantial evidence . . . [and] that *circumstantial evidence can be more than sufficient.*" *Herman & MacLean v. Huddleston*, 459 U.S. 375, 390 n.30 (1983) (emphasis added); *see also, e.g.*, *Seven Cases v. United States*, 239 U.S. 510, 517 (1916) (holding that under food and drug forfeiture

statute, "actual intent to deceive . . . may be derived from the facts and circumstances"); *Rea v. Missouri*, 84 U.S. 532, 543 (1873) ("To establish fraud, it is not necessary to prove it by direct and positive evidence. *Circumstantial evidence is not only sufficient, but in most cases it is the only proof that can be adduced.*" (emphasis added)). The common thread running through these cases is the practical recognition that it is the exceedingly rare case in which an intentionally deceitful party will either admit his intent to deceive or produce direct "smoking gun" evidence of that intent. Therefore, proof of intent by circumstantial evidence is necessary and appropriate to prevent intentional wrongdoers from escaping liability for their deliberate misconduct.

Petitioner fails to acknowledge what it means for a fact finder to infer intent from circumstantial evidence. In a typical patent case, the "circumstances" that bear on whether the concealment of material information was made with intent to deceive (rather than innocently or merely negligently) include the following. First, the knowledge of the applicant is a highly relevant circumstance. If the applicant genuinely was unaware of the information, the concealment of the information cannot have been intentional.[1] There is no dispute here that Dr. Uzan knew that the half-life comparison Petitioner used to argue for patentability involved different doses.

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[1] On the other hand, circumstances evidencing a "cultivate[d] ignorance" or willful disregard for suspicious facts can support an inference of intent. *See Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp.*, 267 F.3d 1370, 1384 (Fed. Cir. 2001).

Second, the significance of the concealed information is plainly relevant. This is a matter of common sense. If the concealed information only marginally bears on the issue of patentability, then it is harder to infer deliberate concealment than it is where the applicant withholds information critical to determining patentability. Where, as here, the information known to the applicant goes directly to the patentability arguments advanced by the applicant, a suggestion that the concealment of the information was innocent or merely negligent is less likely to be credible. Here, the misleading half-life comparison was an important focus of Petitioner's efforts to overcome the examiner's rejection of the claimed formulation as not patentably distinct from the prior art. In the first appeal in this case, the Federal Circuit upheld the district court's summary determination that the undisclosed difference in dose was highly material and further found that the an inference of deceptive intent was reasonable. App. 105a, 108a. Even the dissenting judge on the second appeal joined in this earlier opinion.

The sophistication of the applicant is also germane to determining intent. It is more plausible to infer that the concealment of material information is innocent or merely negligent where the applicant might not have fully appreciated its scientific or legal significance. But where the person responsible for concealing the material information is highly sophisticated and fully appreciates the significance of the withheld information, it is easier to infer intent to deceive. Here, the district court expressly recognized that Dr. Uzan was, as Petitioner stresses, a very experienced and sophisticated scientist. App. 80a. He understood the difference in doses and its

scientific significance. He admitted that he knowingly presented this different dose comparison. App. 52a-53a. The district court also found that he was aware of the Patent Office's evolving objections throughout the prosecution and knew that the examiner was looking for proof of a statistically significant difference between the claimed invention and the prior art. App. 81a. This knowledge and sophistication properly is part of the circumstantial evidence indicative of an intent to deceive.[2]

In addition, the trier of fact is entitled to consider the plausibility of any explanation offered by the patentee for the failure to disclose. The district court here found that the "clinically relevant dose" rationale offered by Dr. Uzan for comparing the claimed compound's half-life with that of the alleged prior art compound at a different dose was

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[2] Because Dr. Uzan was found to have knowledge of the purpose for which the half-life comparison was repeatedly argued to the examiner (App. 81a), this case does not present the issue of whether a conclusion that an applicant "should have known of the materiality" of omitted information can be used in inferring intent. Again, Aventis attempts to insert issues into its Petition that are not presented in this case.

"implausible" and "unreasonable." App. 54a, 67a.[3] The district court could also properly consider the fact that, as noted above, the "excuse" offered by Petitioner for concealing the difference in dosage changed several times during the course of the litigation. The inability to keep a story straight is a time-honored signal of lack of credibility.[4]

The trier of fact also is entitled to consider both evidence of the applicant's good faith as well as the circumstances that might give rise to a motive to deceive the examiner. Every patent applicant has an economic motive to do what it takes to obtain the

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[3] The district court's reliance on credibility determinations, and in particular, the shifting explanations provided by Dr. Uzan for his undisclosed different dose comparison, does not, as Aventis asserts, mean that the district court necessarily and improperly applied a negligence standard. Pet. at 13. *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 208 (1976), cited by Aventis as support for that proposition, has nothing to do with determining intent to deceive in the context of inequitable conduct. *Ernst* involved a statute that provided a "due diligence" defense. *Id.* at 208. That this unrelated statute applies a negligence standard does not somehow transform the consideration in inequitable conduct cases of whether a credible excuse was offered for the material misrepresentation into an improper finding of intent based merely on negligence.

[4] Recognizing these common sense aspects of reasoning from circumstantial evidence does not, as Aventis suggests, shift the burden of proof to the patentee. If, as happened here, the patentee offers excuses and explanations it is entirely reasonable for the court to consider the credibility of those excuses in deciding whether to infer an intent to deceive. The district court explicitly recognized that the defendants had the burden of "affirmatively proving intent . . . at all times." App. 87a.

valuable property rights associated with a patent, and that motive by itself ordinarily is not sufficient to establish intent to deceive. Here, however, Petitioner faced the unusual situation of seeking FDA approval for enoxaparin after the revocation of the European patent protecting the drug and the consequent abandonment of the U.S. counterpart patent application. The district court fairly could consider that the prospect of generic competition shortly after FDA approval, unbuffered by a period of patent-protected monopoly, would give rise to unusual economic pressure to obtain some kind of patent protection by any possible means.

What Petitioner calls the "sliding scale" applied to a determination of intent is nothing more than the common sense drawing of inferences from circumstantial evidence as described in the preceding paragraphs. All things being equal, higher materiality, implausible excuses and an unusually high economic incentive to obtain a patent are circumstances probative of deceptive intent. Petitioner's attempt to label the process of reasoning from circumstantial evidence a "sliding scale" does not change the elements of the claim and the burden of proof. The trier of fact still must determine, after weighing all the circumstances, whether both

materiality and intent have been established by clear and convincing evidence.[5]

Courts regularly uphold inferences of deceptive intent on the basis of this kind of common sense interpretation of circumstantial evidence. For example, in a recent Eighth Circuit bank fraud case, the defendant received a check for $90,700 from an insurance company with which he had never done business. He deposited it into his bank account, which then had a balance of $6, and spent nearly half the money in the next few weeks. The defendant testified that he believed the check was a settlement for a minor car accident in which he was involved a year earlier, but for which he admitted he had never made an insurance claim. Emphasizing the significance of receiving such a large check in the mail and the defendant's incredible explanations for why he thought he was entitled to the money, the court held that a reasonable jury could find intent to defraud beyond a reasonable doubt. *United States v. Peters*, 462 F.3d 953, 959 (8th Cir. 2006); *see also,*

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[5] The Federal Circuit also appropriately allows courts to weigh the levels of materiality and intent in the final equitable balancing step required before reaching a conclusion of inequitable conduct. *Impax Labs.*, 468 F.3d at 1375. This final balancing does not allow inequitable conduct to be based merely on gross negligence. Because that final equitable balancing step occurs only after the threshold findings of materiality and intent have been established by clear and convincing evidence, it cannot lessen the proof necessary to satisfy the intent requirement. Indeed, the primary result of this final balancing step is to provide the court with equitable discretion *not* to find a patent unenforceable even if the court has found both materiality and intent to deceive.

e.g., *United States v. Pennington*, 168 F.3d 1060, 1065 (8th Cir. 1999) ("[P]roof of intent to harm may be inferred from the willful non-disclosure by a fiduciary . . . of material information he has a duty to disclose") (mail fraud and money laundering suit). What Petitioner misleadingly characterizes as a sliding scale that improperly substitutes gross negligence for intent is merely common sense reasoning that the high significance of an event, misstatement or omission and incredible explanations are relevant circumstances in determining whether there was deceptive intent.

B. The Inequitable Conduct Standard Applied in this Case Is Consistent with This Court's Decisions on Inequitable Conduct and on the Doctrine of Unclean Hands.

Petitioner asserts that the doctrine of inequitable conduct should be limited to the facts before the Court in three cases that it decided in the 1930s and 1940s:[6] *Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240 (1933), *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238 (1944) and *Precision Instrument Mfg. Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806 (1945). Pet. at 10-12. The mere fact that adjectives such as "deliberate," "corrupt," "sordid," and "highly reprehensible" appeared in those cases does not mean that these cases established those concepts as a minimum standard for inequitable conduct. There is nothing in these or any other opinions of this Court that suggests that the application of the

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[6] It should be noted, however, that the defense of inequitable conduct existed before these decisions. *See infra* at 28-29 n.10.

doctrine of inequitable conduct is limited to the extreme conduct identified in those cases.

Indeed, the three decisions on which Petitioner relies do not even address the minimum level of culpability needed to constitute inequitable conduct. *Keystone Driller* addressed whether a sufficient nexus existed between the patentee's filing of a false affidavit in a prior litigation and the equitable relief that the patentee sought in a later action to invoke the doctrine of unclean hands. 290 U.S. at 246-47. The Court found such a nexus and upheld application of the unclean hands doctrine to deny an injunction.[7]

Hazel-Atlas addressed a limited procedural question, whether after-discovered inequitable conduct could be used to vacate a judgment entered in a prior term. 322 U.S. at 239. It was not disputed before this Court that Hazel-Atlas and its counsel had committed inequitable conduct and this Court did not discuss the boundaries of that concept.

Precision Instrument likewise did not address the type or degree of misconduct that would constitute inequitable conduct. It held only that the district

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[7] In its *amicus* brief in support of Petitioner, Washington Legal Foundation (WLF) argues that "the court has declined to apply [the] 'unclean hands' doctrine where the plaintiffs' misconduct did not have a sufficiently 'immediate and necessary relation' to the equitable relief sought, to warrant non-enforcement of the patent." WLF Br. at 17 (quoting *Keystone Driller*). WLF does not explain what this principle has to do with this case and ignores the fact that the misleading half-life comparison at issue here was repeatedly argued by Petitioner to support patentability over repeated rejections by the PTO, thus establishing a significant relationship between the inequitable conduct and the unenforceability relief imposed.

court properly dismissed the complaints for patent infringement based on the doctrine of unclean hands. 324 U.S. at 820. Nowhere did this Court suggest that it was establishing a minimum level of culpability needed to constitute inequitable conduct. It should be noted, however, that this Court expressly recognized that inequitable conduct was not limited to "fraud," much less the "corrupt, sordid and highly reprehensible" fraud standard that Petitioner suggests should apply. *Id.* at 816 (referring to "fraud *or other inequitable conduct*" constituting unclean hands (emphasis added)).

Petitioner also argues that the standard for inequitable conduct must be "corrected" because it does not contain a reliance element as is required for common law fraud. Pet. at 26. Petitioner raised no such argument below. In any event, the lower courts in this case did not apply a separate reliance requirement when analyzing the claim of inequitable conduct because, under this Court's inequitable conduct and unclean hands precedents, there is none. Unclean hands is a defense premised on the long-standing principle that courts of equity will not provide a remedy to plaintiffs who have not themselves behaved equitably. *See Precision Instrument*, 324 U.S. at 814 ("a self-imposed ordinance that closes the doors of a court of equity to one tainted with inequitableness or bad faith relative to the matter in which he seeks relief").

Moreover, quite apart from the historical reasons why reliance was not an element of the unclean hands defense, recognition of a reliance factor would seriously undermine the disincentive to inequitable conduct. This Court has stressed the importance of maintaining such a disincentive:

> "The far-reaching social and economic consequences of a patent, therefore, give the public a paramount interest in seeing that patent monopolies spring from backgrounds free from fraud or other inequitable conduct and that such monopolies are kept within their legitimate scope." *Id.* at 816.

A patent applicant will be more likely to conceal material information during patent prosecution if an accused infringer would have to prove not only the concealment of the information, but also that the information would have prevented the issuance of the patent. It often is difficult to predict how an examiner would have responded to the concealed information. Moreover, the claims might have been narrowed in light of the concealed information. An effective patent system requires that examiners, not district court judges, consider material information in the first instance. Imposing a reliance requirement would make it even more likely that patent applicants would conclude that they could get away with not disclosing material information. Applicants easily could decide that they would have the opportunity, if inequitable conduct were raised, to convince a district court judge not familiar with patent prosecution that the patent would have issued anyway.

C. There is No "Circuit Split" or "Split" in Federal Circuit Authority With Respect to What Is Required to Prove the Intent Element of Inequitable Conduct.

Petitioner contends that this Court should grant the petition because there was a split in authority among the regional circuits prior to the creation of the Federal Circuit in 1982 concerning the mental

state required to establish a claim of inequitable conduct. This argument makes no sense. There is no "circuit split" for the Court to resolve with respect to the application of the doctrine of inequitable conduct in proceedings before the Patent Office. This is an issue that is governed by Federal Circuit law, not the law of the regional circuits. The Federal Circuit has required proof of intent to deceive at least since its *en banc* decision in *Kingsdown*.

Nor is there any merit to Petitioner's contention that an "intra-circuit" split exists between panels of the Federal Circuit with regard to the proper standard for claims of inequitable conduct. The Federal Circuit decisions that Petitioner cites as examples of a failure to comply with *Kingsdown* are nothing more than additional examples where all facts and circumstances were considered, including the high materiality of information not disclosed to the Patent Office, in determining whether intent to deceive was established. *See Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1313 (Fed. Cir. 2008) ("The required showings of materiality and intent are separate, and a showing of materiality alone does not give rise to a presumption of intent to deceive.") (citing *Kingsdown*); *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1190-91 (Fed. Cir. 2006) ("Even if an omission is found to be material, the omission must also be found to have been made with the intent to deceive. '[M]ateriality does not presume intent, which is a separate and essential component of inequitable conduct.'") (quoting *GFI, Inc., v. Franklin Corp.*, 265 F.3d 1268, 1274 (Fed. Cir. 2001)). The fact that different appellate judges have reached different conclusions when reviewing the same factual record also does not establish that there is a

split on the proper legal standards that needs to be addressed by this Court.

II. The Question on which Petitioner Seeks Review Is Not Presented by this Case Nor Was It Raised Below.

A. Neither the District Court Nor the Federal Circuit Improperly Conflated Materiality and Intent So As To Allow Inequitable Conduct To Be Proven Merely by Gross Negligence.

Petitioner ignores that the district court carefully considered the full range of circumstantial evidence available, not just the high materiality of the omissions from Dr. Uzan's affidavits, in concluding that there was intent to deceive the Patent Office, not just negligence. What Petitioner is really challenging are the district court's credibility determinations and the sufficiency of the circumstantial evidence the district court relied on in this case. As detailed in the Counterstatement and Part I of the Argument, the circumstantial evidence was more than sufficient to support the district court's inference by clear and convincing evidence that Dr. Uzan concealed the difference in dose with intent to deceive the examiner. Petitioner asks this Court to second guess the district court's careful factual findings. A panel of the Federal Circuit Court of Appeals already undertook the proper clear error analysis and affirmed the factual findings of the district court. This Court is not and should not be in the business of granting petitions for certiorari merely to conduct a second clear error review of facts found by the district court.

B. The Legal Question Petitioner Seeks To Present Was Not Raised Below.

Contrary to Petitioner's assertion, this case does not "present[] a sound vehicle for shaping the inequitable conduct doctrine" (Pet. at 28) because the issues Petitioner now presents for review were not considered by the district court or either of the two Federal Circuit panels below. Accordingly, the Court should apply its "traditional rule" and decline to grant certiorari because the issues raised in the petition were not "pressed or passed upon below." *United States v. Williams*, 504 U.S. 36, 41 (1992) (quoting *Duignan v. United States*, 274 U.S. 195, 200 (1927)).

Petitioner never argued to the district court or the Federal Circuit at any point prior to its petition for rehearing *en banc* that the standards used to determine inequitable conduct were inconsistent with this Court's precedents. None of Petitioner's briefs to the district court or the Federal Circuit on direct appeal cited *Hazel-Atlas*, *Precision Instrument Manufacturing*, or *Keystone Driller*, cases that Petitioner now asserts render the lower courts' judgments erroneous. Similarly, Petitioner never argued in its briefs to the district court or the Federal Circuit panels that the legal standards they applied to the defendants' inequitable conduct claim were inconsistent with the *Kingsdown* decision's requirement that a defendant prove intent, not gross negligence.

In its petition for panel rehearing and rehearing *en banc*, Petitioner for the first time sought to recast its position as a challenge to the applicable legal standard. It is telling that of the 52 cases cited in the Petition, only three were cited in the Brief for

Plaintiff-Appellants in the second Federal Circuit appeal on the issue of intent. The Federal Circuit properly declined to review *en banc* a panel decision based on issues that were never raised before the panel. Not even the judge who dissented on the panel voted to take this case *en banc*. This Court should also decline review. This Court "sits as a court of review," and should not accept Petitioner's invitation to grant certiorari to parse the factual determinations of the district court, or to effect dramatic changes to the law of inequitable conduct based on questions "not pressed or passed upon below."

Although one judge of the Federal Circuit has recently suggested that "the time has come to review [the test for inferring deceptive intent] en banc," *Larson Mfg. Co. of S. D., Inc. v. Aluminart Prods. Ltd.*, Nos. 2008-1096, 2008-1174, 2009 WL 691322 (Fed. Cir. Mar. 18, 2009) (Linn, J., concurring), this case, in which intent was appropriately inferred from all the evidence and a challenge to the legal standards for determining intent was not presented below, is not an appropriate vehicle for this Court to consider issues concerning intent to deceive.

III. The Inequitable Conduct Defense Is Crucial to Ensuring the Integrity of Our *Ex Parte* Patent Prosecution System.

Based on a reading of only the Petition and the briefs of the *amici*, one might conclude that the inequitable conduct defense serves no useful purpose, but merely drains the resources of litigants and the judiciary. In fact, as even Judge Rader recognized in dissent in this case, the inequitable conduct doctrine is the only effective mechanism available to ensure the integrity of an *ex parte* patent

prosecution system. Contrary to the assertions of Petitioner and its *amici*, there is no "plague" resulting from the defense of inequitable conduct. Important safeguards exist that appropriately limit the application of the defense and give courts the equitable discretion to decline to apply the defense of patent unenforceability, even when a defendant proves materiality and intent to deceive by clear and convincing evidence.

A. The Inequitable Conduct Defense Is the Only Effective Method of Enforcing the Duty of Candor Owed to the Patent Office.

A patent applicant must persuade the examiner that the claimed invention satisfies various statutory requisites, including utility, novelty and non-obviousness. 35 U.S.C. §§ 101-103. The process is *ex parte*. No one involved in the prosecution of the patent has an economic incentive to uncover problematic prior art or other potentially invalidating information and bring it to the examiner's attention.

The examiners themselves are charged with searching the pertinent scientific literature to determine whether the claimed invention really is novel and non-obvious. But the reality is quite different. It is widely recognized that examiners have insufficient time and resources to undertake a comprehensive search for invalidating prior art. *See* Doug Litchman & Mark A. Lemley, *Rethinking Patent Law's Presumption of Validity*, 60 STAN. L. REV. 45, 46, 53-54 (2007). The PTO has acknowledged that "the volume of patent applications continues to outpace our capacity to examine them. We have a pending application

backlog of historic proportions."[8] *See also* Statement of Robert D. Budens, President, Patent Office Professional Association, to House Judiciary Committee's Subcommittee on Courts, the Internet and Intellectual Property at 10-11 (Feb. 27, 2008) (although the average number of claims per issued patent has grown significantly from 1975 to 2005, the amount of time allotted for each examination has remained static, resulting in insufficient time for examinations).[9]

Moreover, much of the information material to patentability simply is not available to the examiner if the applicant fails to disclose it. For example, although no patent may issue for a claimed invention that was on sale more than one year before the filing of the patent application, 35 U.S.C. § 102(b), the examiner will rarely know about the applicant's commercial activities.

Similarly, examiners often reject as *prima facie* obvious claims to chemical compounds that are structurally similar to compounds with similar properties disclosed in the prior art unless the applicant can show that the claimed compound has unexpectedly superior properties. *See In re Dillon*,

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[8] U.S. Patent & Trademark Office, 2007-2012 Strategic Plan at 6 (2007) ("PTO Strategic Plan"), available at http://www.uspto.gov/web/offices/com/strat2007/stratplan2007-2012.pdf (last visited Mar. 23, 2009) The PTO reports a five-fold increase in the number of pending applications between 1987 and 2007. U.S. Patent & Trademark Office, Performance and Accountability Report, FY 2007, table 5 (2007), http://www.uspto.gov/web/offices/com/annual/2007/50303_table3.html (last visited Mar. 23, 2009).

[9] http://judiciary.house.gov/hearings/pdf/Budens080227.pdf (last visited Mar. 23, 2009).

919 F.2d 688, 692-93 (Fed. Cir. 1990) (*en banc*). The applicant is typically the only source for test data to demonstrate such superiority. If the applicant "cherry picks" favorable data to suggest a superiority that the applicant's unpublished data as a whole does not support, there is little chance that the examiner will discover the unfavorable data or be able to make a fully informed assessment of the claimed compound's ostensible superiority. *See Cargill, Inc. v. Canbra Foods, Ltd.*, 476 F.3d 1359, 1365 (Fed. Cir. 2007).

The temptation to conceal material information from the examiner is especially great in the pharmaceutical industry. Pharmaceutical patents that cover commercial drug products are extremely valuable. The introduction of generic competition generally results in the generic products quickly capturing most of the market for the drug in question. Henry Grabowski, *Competition between Generic and Branded Drugs, in* PHARMACEUTICAL INNOVATION: INCENTIVES, COMPETITION AND COST-BENEFIT ANALYSIS IN INTERNATIONAL PERSPECTIVE 153, 160 (Frank A. Sloan & Chee-Ruey Hsieh, eds., 2007). Moreover, if the owner of a pharmaceutical patent sues a generic drug company for patent infringement within time frames specified by statute, the FDA automatically is precluded from approving the generic company's product for sale for 30 months. 21 U.S.C. § 355(j)(5)(B)(iii). Thus, the owner of even a weak or invalid pharmaceutical patent can obtain what amounts to a two and a half year preliminary injunction against generic competition without any assessment of the likelihood of success on its infringement claim.

Given patent applicants' lack of incentives to disclose prior art or other problematic information known to the applicant, and the limited ability of increasingly overworked patent examiners to uncover such information on their own, the integrity of the *ex parte* patent prosecution system requires a mechanism to enforce the duty of candor that patent applicants owe to the Patent Office. Congress has long recognized the defense of patent unenforceability based on inequitable conduct before the Patent Office to be the primary enforcement mechanism.[10]

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[10] In the Patent Act of 1790, Congress specifically empowered "district court" judges to "repeal" within one year of issuance patents obtained "surreptitiously by, or upon false suggestion." Act of Apr. 10, 1790, ch. 7, § 5, 1 Stat. 109, 111 (1790).

The Patent Act of 1836 established the Patent Office and charged it with examining patent applications. Patent Act of 1836, ch. 357, §§ 1, 5-7, 5 Stat. 117, 117-20 (1836). Although the 1836 Patent Act eliminated the right to bring an affirmative action to seek the repeal of an issued patent, it still allowed a party sued for infringement to assert as a defense that the patent had been "surreptitiously or unjustly obtained." *Id.* at § 15, 5 Stat. 117, 123.

In 1870, Congress again recognized the right of an accused infringer to challenge a patent containing "less than the whole truth" concerning the invention or obtained "surreptitiously or unjustly" and to assert "like defenses" against infringement. Patent Act of 1870, ch. 230, § 61, 16 Stat. 198, 208 (1870).

The 1952 Codification of the Patent Act specifically identified unenforceability as one of the available defenses to infringement. Section 282 of Title 35, which Congress has not materially amended since 1952, provides: "The following shall be defense in any action involving the validity or infringement of a patent and shall be pleaded: (1) Noninfringement, absence of liability for infringement or *unenforceability* . . . ." 66 Stat. 792, 812 (July 19, 1952) (emphasis added). By 1952, the term

Only an accused patent infringer has the resources and incentive to prove a breach of this duty. Other methods of policing the duty of candor owed to the Patent Office have proven ineffective and unworkable. The Patent Office, for a period, established a "fraud squad,"[11] *i.e.*, a group of "examiners with legal training assigned to the Office of the Assistant Commissioner for Patents" to whom issues of fraud or inequitable conduct could be referred. Notice of Rule-Making, May 19, 1982, 47 Fed. Reg. 21746 (May 19, 1982) (reprinted in 37 C.F.R. § 1.56 (1982)).

The "fraud squad" was short-lived. In October 1988, the PTO announced that its examiners would no longer investigate deceptive intent due to "the lack of tools in the Office to deal with this issue." *Patent and Trademark Office Implementation of 37 C.F.R. § 1.56,* 1095 OFF. GAZ. PAT. OFFICE 16 (Oct. 11, 1988). The PTO concluded that "[a] court, with subpoena power, is presently the best forum to consider duty of disclosure issues under the present

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unenforceability as used by the courts referred to deliberately withholding information from the PTO. *See, e.g., Ingersoll Milling Mach. Co. v. Gen. Motors Corp.*, 110 F. Supp. 12, 34-35 (N.D. Ill. 1952).

[11] *Nilssen v. Osram Sylvania, Inc.*, 440 F. Supp. 2d 884, 898 (N.D. Ill. 2006).

evidentiary standard for finding an 'intent to mislead.'" *Id.*[12]

B. There is No "Plague" Resulting from the Inequitable Conduct Defense.

The only authority that Petitioner cites for its statement that the inequitable conduct defense is asserted in "virtually every patent infringement case" and that it consequently has become a "plague" is that "the Federal Circuit has decided no fewer than 42 inequitable conduct cases over the past three years." Pet. at 24-25. According to the caseload statistics published by the Federal Circuit, that constitutes approximately 5 percent of the total number of appeals in patent cases that were adjudicated on the merits in the Federal Circuit during the court's last three fiscal years.[13] Even under Petitioner's inflated rhetoric, 5 percent of all patent appeals can hardly constitute a "plague."

The PATSTATS Database maintained by the University of Houston Law Center, a database of the

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[12] The problem of inequitable conduct cannot be addressed by separate tort or antitrust litigation against or criminal prosecution of the perpetrators of inequitable conduct. Separate civil litigation would require duplicative relitigation of the issues raised in the infringement suit and it is difficult to imagine that prosecuting patent lawyers and inventors for inequitable conduct would be a priority for the criminal justice system. The only practical forum in which to enforce the patent applicant's duty of disclosure is in the action in which the patentee seeks to enforce the patent.

[13] The Federal Circuit reports that during its three fiscal years from 2006-2008, 82[illegible] patent cases were adjudicated on the merits. *See* http://www.cafc.uscourts.gov/statistics.html (Caseload by Category, Table of Data to accompany pie charts) (last visited Mar. 23, 2009).

dispositions of patent infringement actions, which Petitioner cited in its Petition for Rehearing *En Banc* to the Federal Circuit in this case, similarly shows that the courts have addressed the inequitable conduct defense on the merits in only a modest percentage of recent patent infringement decisions. The data reported since 2006 show that approximately 13.5% of decisions in patent infringement actions have included an actual adjudication of the inequitable conduct defense, either by summary judgment or at trial.[14] While the defense of inequitable conduct is likely pleaded in a higher percentage of cases, the fact that it is addressed on the merits in fewer than one out of seven decisions demonstrates that the courts and

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[14] Out of the universe of patent infringement decisions tracked by the PATSTATS database, 43 out of the 359 decisions from 2006 and 65 out of the 439 decisions from 2007 addressed a claim of inequitable conduct either through summary judgment or after trial. *See* http://www.patstats.org/2006.htm (last visited Mar. 24, 2009); http://patstats.org/2007%20full%20year.htm (last visited Mar. 24, 2009); http://www.patstats.org/Cumulative Caselist through 3Q08.xls (last visited Mar. 24, 2009).

litigants are not being choked with a "plague" of litigation over the inequitable conduct defense.[15]

The modest percentage of patent infringement actions in which the inequitable conduct defense is addressed on the merits also tends to show that the checks that exist to prevent the pleading of unfounded claims of inequitable conduct and that permit their disposition early in a litigation are working. A number of safeguards exist. Initially, the defense of inequitable conduct must be pleaded with the same particularity as fraud under Rule 9(b) and inadequately pleaded claims may be dismissed at the outset of a case. Fed. R. C. P. 9(b); *See also Central Admixture Pharm. Servs., Inc. v. Advanced Cardiac Solutions, P.C.*, 482 F.3d 1347, 1356-57 (Fed. Cir. 2007). Indeed, before a pleading is ever filed, counsel must satisfy its obligations under Rule 11 to ensure that any inequitable conduct charges have the requisite legal and evidentiary support. Fed. R. Civ. P. 11. Far from permitting a reflexive pleading of inequitable conduct in every case, the

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[15] Aventis's argument that patent quality decreases because the alleged "proliferation of inequitable conduct charges gives patent applicants strong incentives to inundate the PTO with information in the hopes of forestalling an inequitable conduct charge" is without merit. Pet. at 28. The Patent Office Professional Association (POPA), a professional association of PTO examiners—the group that Aventis seeks to protect from being inundated—has told Congress that it believes that any weakening of the inequitable conduct defense would make the PTO's job more difficult by "remove[ing] . . . the enforcement mechanism" that maintains the quality of applicant disclosures. Patent Office Professional Association, Congressional White Paper, The Patent Reform Act Will Hurt, Not Help, the U.S. Patent System (Aug. 2007), *available at* http://www.piausa.org/patent_reform/articles/the_patent_reform_act_will_hurt_not_help_the_u_s_patent_system.

requirements of Rules 9(b) and 11 typically force defendants to wait until after obtaining discovery before asserting an inequitable conduct defense, as the defendants did in this case. As discussed above, if a claim of inequitable conduct proceeds to resolution by a district court on summary judgment or by trial, the defendant faces elevated evidentiary standards, and must prove materiality and intent by clear and convincing evidence. Even if a district court finds that a defendant has met that burden, it is obligated to consider separately whether the facts warrant the exercise of the courts' equitable discretion to grant the defense of unenforceability.[16] *eSpeed, Inc. v. BrokerTec USA, L.L.C.*, 480 F.3d 1129, 1135 (Fed. Cir. 2007). Collectively, these safeguards—a strict pleading standard, an elevated burden of proof, and a requirement that courts

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[16] *Amici curiae* argue that the Court should grant the petition for certiorari in order to correct what WLF describes as a "fundamental deficiency"—that a finding of inequitable conduct results in the defense of unenforceability, not a menu of possible remedies. As an initial matter, the issue of what remedies should be available for inequitable conduct is beyond the scope of the question presented by the Petition. Moreover, as discussed above in the text, district courts are obligated to weigh the equities to determine whether unenforceability is warranted, even when a defendant has proven the elements of inequitable conduct by clear and convincing evidence. District courts thus have significant discretion to limit the application of the defense to cases in which unenforceability is warranted based on the equities. Furthermore, WLF's and Nilsson's arguments fail to recognize that unenforceability is defined in the Patent Act as a defense. 35 U.S.C. § 282. The outcome of proving any defense, be it laches, the expiration of a statute of limitations or inequitable conduct, is that it provides a defense to the claim asserted.

undertake an additional analysis as to whether all the facts and circumstances warrant the remedy of unenforceability—guard against any risk that honest holders of valid patents will find themselves unable to enforce those patents.

CONCLUSION

For the foregoing reasons, this Court should deny the petition.

Respectfully submitted,

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